DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 2 4 2010

Re: MOZOBIL
Docket No.: FDA-2009-E-0164

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 5,583,131, filed by Genzyme Corporation, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for MOZOBIL (plerixafor), the human drug product claimed by the patent.

The total length of the regulatory review period for MOZOBIL (plerixafor) is 3,849 days. Of this time, 3,666 days occurred during the testing phase and 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 4, 1998.

   The applicant claims June 3, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 4, 1998, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 16, 2008.

   FDA has verified the applicant's claim that the new drug application (NDA) 22-311 was submitted on June 16, 2008.

3. The date the application was approved: December 15, 2008.

   FDA has verified the applicant's claim that NDA 22-311 was approved on December 15, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Charles E. Van Horn
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